UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

STATE OF NEW YORK, STATE OF ILLINOIS, STATE OF MARYLAND, STATE OF WASHINGTON,

Plaintiffs,

- against -

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES.

Defendant.

07-CV-8621 (PAC) (RLE)

ECF Case

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS AND IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

			P	age
TABL	E OF A	AUTHO	PRITIES	. iii
PREL	IMINA	RY STA	ATEMENT	1
SUMI	MARY	OF AR	GUMENT	3
STAT	EMEN	T OF F	ACTS	4
	Statut	ory and	Regulatory Background	4
	The P	laintiff	States' SCHIP Programs	8
	i.	New Y	York's SCHIP Plan	8
	ii.	Washi	ington's SCHIP Program	. 10
	iii.	Maryl	and's SCHIP Program	. 11
	iv.	Illinoi	is's SCHIP Program	. 13
	The A	august 1	7 Letter	. 13
			sapproves New York Plan Based on the Requirements	. 14
	Other	Effects	of the August 17 Letter	. 15
ARGU	JMENT	Γ		. 16
I.			T HAS SUBJECT-MATTER JURISDICTION OVER	. 16
	A.	This I	Dispute Is Ripe for Judicial Resolution	. 16
		1.	The August 17 Letter Has Had an Immediate, Substantial and Concrete Impact Upon the Plaintiff States	
		2.	Issuance of the August 17 Letter Constituted Final Action	. 21
		3.	The Issues Are Purely Legal	. 25

		4.	Revie	w Would Neither Impede Nor Delay Enforcement of SCHIP Rules 26
		5.	This C	Court Has an Adequate Factual Record
	B.			Review Scheme Does Not Preclude Plaintiffs From Seeking nent Review of the Directives in the August 17 Letter
	C.			tatute Does Not Provide an Adequate Alternative to
II.	THE A	AUGUS	ST 17 L	ENTITLED TO A DECLARATORY JUDGMENT THAT ETTER IMPOSES INVALID MANDATES AND
	A.			ns Need Only Meet Requirements of Statutes or Codified
	B.	Const	itute Le	s and Requirements of Defendant's August 17 Letter gislative Rules, Which May Be Adopted Only After omment Rule-Making
		1.		anguage of the August 17 Letter Demonstrates Defendant's To Bind the States
		2.		dant's Conduct Demonstrates Its Intent To Treat the rements of the August 17 Letter as Binding Obligations
		3.		equirements of the August 17 Letter Have Immediate Binding s on the States
		4.		ugust 17 Letter Is a New Position Inconsistent With Existing ations
		5.		ugust 17 Letter Is Not a Mere General Policy Statement or retive Rule
			a.	General statements of policy may not impose a new binding norm
			b.	Interpretive statements may not impose new requirements 46
CONO	CLUSIC	N		49

TABLE OF AUTHORITIES

Cases	Page
Abbott Laboratories v. Gardner, 387 U.S. 136 (1967)	passim
4ble v. U.S., 88 F.3d 1280 (2d Cir. 1996)	17, 32
Alaska v. Department of Transport, 868 F.2d 441 (D.C. Cir. 1989)	35
Amer. Acad. of Religion v. Chertoff, 463 F. Supp.2d 400 (S.D.N.Y. 2006)	17, 21
American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106 (D.C. Cir. 1993)	34
Appalachian Power Co. v. E.P.A., 208 F.3d 1015 (D.C. Cir. 2000)	37, 41
Aquavella v. Richardson, 437 F.2d 397 (2d Cir. 1971)	17, 25
Batterton v. Marshall, 648 F.2d 694 (D.C. Cir. 1980)	33
Bennett v. Spear, 520 U.S. 154 (1997)	21
Bowen v. City of New York, 476 U.S. 467 (1986)	29, 30
California v. Shalala, 166 F.3d 1019 (9th Cir. 1999)	30
Chamber of Commerce v. Dept. of Labor, 174 F.3d 206 (D.C. Cir. 1999)	34, 44
Chrysler Corp. v. Brown, 441 U.S. 281 (1979)	34, 35

Coit Independence Joint Venture v. Federal Savings and Loan Insurance Corporation, 489 U.S. 561 (1989)	0
Columbia Broadcasting System, Inc. v. United States, 316 U.S. 407 (1942)	.5
Community Nutrition Inst. v. Young, 818 F.2d 943 (D.C. Cir. 1987)	.5
CropLife America v. E.P.A., 329 F.3d 876 (D.C. Cir. 2003) passin	m
Davidson v. Glickman, 169 F.3d 996 (5th Cir. 1999)	.0
Diamond Shamrock Corp. v. Costle, 580 F.2d 670 (D.C. Cir. 1978) 2	0,
<i>Ehrenfeld v. Mahfouz</i> , 489 F.3d 542 (2d Cir. 2007)	6
General Electric Co. v. E.P.A., 290 F.3d 377 (D.C. Cir. 2002)	5
Gibson v. Berryhill, 411 U.S. 564 (1973)	1
Hoctor v. Dep't of Agriculture, 82 F.3d 165 (7th Cir. 1996)	.7
Houghton v. Shafer, 392 U.S. 639 (1968)	1
Matthews v. Eldridge, 424 U.S. 319 (1976)	9
McLouth Steel Products Corp. v. Thomas, 838 F.2d 1317 (D.C. Cir. 1988) 34, 4	6
McNary v. Haitian Refugee Ctr., 498 U.S. 479 (1991)	0

Medimmune, Inc. v. Genentech, Inc., 127 S. Ct. 764 (2007) 2	20
Morton v. Ruiz, 415 U.S. 199 (1974)	33
Motor Vehicle Manufacturers Ass'n of the U.S., Inc. v. State Farm Mut. Automobile Ins. Co., 463 U.S. 29 (1983)	25
N.Y. Mercantile Exchange v. Commodity Futures Trading Comm'n, 828 F. Supp. 186 (S.D.N.Y. 1993)	7
Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs, 417 F.3d 1272 (D.C. Cir. 2005)	26
Nat'l Mining Ass'n v. Dept. of Labor, 292 F.3d 849 (D.C. Cir. 2002)	30
Occidental Chemical Corp. v. F.E.R.C., 869 F.2d 127 (2d Cir. 1989)	7
Pacific Gas & Electric Co. v. F.P.C., 506 F.2d 33 (D.C. Cir. 1974) 44, 45, 4	16
Rodway v. Dept. of Agriculture, 514 F.2d 809 (D.C. Cir. 1975) 3	33
Ruiz-Martinez v. Mukasey, 516 F.3d 102 (2d Cir. 2008)	30
Shalala v. Guernsey Memorial Hospital, 514 U.S. 87 (1995)	Ю
Simmonds v. I.N.S., 326 F.3d 351 (2d Cir. 2003)	9
Skubel v. Fuoroli, 113 F.3d 330 (2d Cir. 1997)	32
Steffel v. Thompson, 415 U.S. 452 (1974)	20

Sweet v. Sheahan, 235 F.3d 80 (2nd Cir. 2000)
Syncor Intern. Corp. v. Shalala, 127 F.3d 90 (D.C. Cir. 1997)
Thomas v. Union Carbide Agric. Prods. Co., Inc., 473 U.S. 568, 581 (1985)
Thunder Basin Coal Co. v. Reich, 510 U.S. 200 (1994)
U.S. Gypsum Co. v. Muszynski, 209 F. Supp. 2d 308 (S.D.N.Y. 2002)
<i>U.S. Telephone Association v. F.C.C.</i> , 28 F.3d 1232 (D.C. Cir. 1994)
United States v. Picciotto, 875 F.2d 345 (D.C. Cir. 1989)
United States v. Yuzary, 55 F.3d 47 (2d Cir. 1995)
Whitman v. American Trucking Assns. 531 U.S. 457 (2001)
Yesler Terrace Cmty. Council v. Cisneros, 37 F.3d 442 (9th Cir. 1994)
Federal Statutes
5 U.S.C. § 500 et seq
5 U.S.C. § 706(2)
5 U.S.C. § 701, et seq
8 U.S.C. § 1252(a)(5)
28 U.S.C. § 1331
42 U.S.C. § 1316
42 U.S.C. § 1397bb(b)
42 U.S.C. § 1397ff(c)(1)
42 U.S.C. § 1397gg(e)(2)
42 U.S.C. § 1397jj(b)

42 U.S.C. § 9902(2)
Title XXI, Pub. L. No. 105-33, title IV, sec. 4901
Title XXI
Federal Register
36 Fed. Reg. 2532 (Feb. 5, 1971)
64 Fed. Reg. 60922 (Nov. 8, 1999)
66 Fed. Reg. 2602-04 (Jan. 11, 2001)
66 Fed. Reg. 2602 (Jan. 11, 2001)
66 Fed. Reg. 2604 (Jan. 11, 2001)
72 Fed. Reg. 3147
72 Fed. Reg. 68888
72 Fed. Reg. 73708
73 Fed. Reg. 3971
Federal Rules and Regulations
45.655.00044
45 C.F.R. § 92.11
42 C.F.R. § 457.1
42 C.F.R. § 457.10
42 C.F.R. § 457.204(d)(3)
42 C.F.R. § 457.320(a)
42 C.F.R. § 457.350
42 C.F.R. § 457.503(a)
42 C.F.R. § 457.805
42 C.F.R. § 457.810
42 C.I.R. § 437.010
Illinois Statutes
215 ILCS 106/1
215 ILCS 106/20(a)(2)
215 ILCS 106/30(a)(2)
215 ILCS 170/1
New York Statutes
N.Y. McKinney's Pub. Health Law § 2511(2)(a)(ii)

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PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS AND IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Plaintiffs, the States of New York, Illinois, Maryland and Washington ("the Plaintiff States"), submit this Memorandum in opposition to the motion of Defendant, the United States Department of Health and Human Services, to dismiss the Complaint and in support of the motion of the Plaintiff States for partial summary judgment.

PRELIMINARY STATEMENT

In this action, the Plaintiff States challenge new requirements that the Defendant, the United States Department of Health and Human Services (HHS), through its Centers for Medicare and Medicaid Services (CMS), suddenly imposed under the State Children's Health Insurance Program (SCHIP) by a letter to State SCHIP Directors dated August 17, 2007 ("the August 17 Letter"), effecting wholesale changes in the operation of state SCHIP programs without the normal publication of notice and opportunity for comment that are required for legislative rule-making. The Plaintiff States submit that because these new directives impose significant and mandatory changes

from prior regulations and practice and appear to be in excess of the provisions of the SCHIP statute, they were required to be subjected to the normal rule-making process, including notice and comment. Defendant's failure to utilize these processes has resulted in the imposition of provisions that are unattainable, outside the control of the states and poorly suited to achieve even the stated goals of the Defendant, issues that could have been, and may still be, addressed in the deliberative process incident to proper rule-making. The provisions in the August 17 Letter will deprive the States of federal funding that could be used to provide health insurance for a substantial number of children who need and would benefit from their respective SCHIP programs and who are in the group that SCHIP was enacted to assist, namely children in families who are ineligible for Medicaid but who cannot afford private health insurance.

It is difficult to discuss the SCHIP programs and the impact of the August 17 Letter without touching on these issues of public health care policy. Indeed, in their Amended Complaint the Plaintiff States seek, as alternative relief, a declaration that the directives in the August 17 Letter are contrary to and not reasonably related to the purposes of the SCHIP statute and Defendant's own rulemaking policy. However, it is not necessary at this time for the Court to decide those issues. On the indisputable facts surrounding the issuance of the August 17 Letter and Defendant's subsequent communications with the affected States concerning it, the Court should grant partial summary judgment in favor of the Plaintiff States on their claims that the Letter was improperly issued in the absence of rule-making procedures, and that Defendant should be enjoined from enforcing it. Plaintiff States are not asking the Court to decide questions of health policy. To the extent there may be philosophical or political issues that divide the parties, Plaintiffs respect the right of the Defendant, and of the federal administration of which it is a part, to establish its priorities as it sees

fit. The Plaintiff States seek only to require that proper procedure be followed and that the drastic mandates contained in the August 17 Letter not be imposed on any state without affording them an opportunity for the notice-and-comment period that is a normal and necessary part of such rulemaking. They hope that such input by the states and other interested parties will inform the Defendant's decision-making process in a constructive way to produce a practical and less draconian result.

SUMMARY OF ARGUMENT

Defendant's motion to dismiss on jurisdictional grounds should be denied. This case is ripe for judicial resolution because (1) the August 17 Letter has had and is now having an immediate, substantial and concrete effect on the Plaintiff States, in terms of funds lost, children that cannot be insured or both; (2) the August 17 Letter constituted final agency action, both by its own terms and the evidence of CMS's follow-up communications; (3) the issues to be litigated include (a) whether the Letter is a legislative rule and whether it was issued in violation of law, both purely legal issues that can be decided now, and (b) whether the rules announced in the Letter were arbitrary, capricious and contrary to law, an issue that can be determined by the Court if necessary with limited discovery and without a more developed administrative record; (4) review by this Court would in no way impede the enforcement of the SCHIP legislative and regulatory scheme; and (5) the Court has an adequate factual record to determine the case.

Contrary to Defendant's contention, the statutory review scheme incorporated into the SCHIP statute does not preclude the Plaintiff States from seeking review in this Court of the directives contained in the August 17 Letter. That statutory review scheme, which is not exclusive under the terms of the relevant statutes, permits only a request for reconsideration and then appeal to a federal

appeals court of the disapproval of a particular state's SCHIP plan or plan amendment. The scheme does not apply to the collateral issue here — a facial challenge to the validity of the new broad (and nationwide) requirements in the August 17 Letter. Moreover, the review process provided by the statute, which a Plaintiff cannot even invoke unless and until it submits a plan for approval and it has been denied, is inadequate in any event because Defendant has clearly expressed its refusal to consider changing the new requirements and the administrative procedure would be futile.

Defendant's motion to dismiss the Plaintiffs' "rule-making" claim for failure to state a claim should be denied and Plaintiffs should be granted summary judgment on that claim, remanding this matter to HHS for invocation of the procedures properly applicable to legislative rulemaking, in which instance there would not be a need for this court to reach Plaintiffs' second claim that the new rules are arbitrary and capricious under the Administrative Procedure Act. That the directives in the August 17 Letter are legislative rules is confirmed by (1) the language of the Letter itself; (2) Defendant's conduct that demonstrates its intent to treat them as binding obligations; (3) the binding effect they have on the Plaintiff States; and (4) their inconsistency with existing regulations. The Letter is not a "general statement of policy" or "interpretive rule," as Defendant contends, and should thus be ordered to be subjected to legislative rule-making procedures.

STATEMENT OF FACTS

Statutory and Regulatory Background

Congress enacted SCHIP in 1997 as Title XXI of the Social Security Act (Title XXI). Pub. L. No. 105-33, title IV, sec. 4901(a). SCHIP is a joint federal-state program. Declaration of Judith Arnold ("Arnold Decl.") ¶ 4. Under SCHIP, states provide health coverage to uninsured children in families who are ineligible for Medicaid but still cannot afford other health insurance, and the

federal government reimburses the states for a substantial portion of their expenditures. *Id.* The federal government makes matching funds available to states with approved SCHIP plans through capped allotments, based on a formula that takes into account the number of low-income children in a state. *Id.* Each state is allotted a specific maximum amount that it can receive as matching funds during each federal fiscal year. 42 U.S.C. § 1397dd.

From the inception of the program and through August 17, 2007, the SCHIP statute and implementing regulations have been interpreted and applied to afford participating states with considerable flexibility in how they comply with general federal requirements for providing health insurance coverage to children. Declaration of Cynthia R. Mann ("Mann Decl.") ¶ 7. States may establish eligibility rules, including those relating to income and resources. 42 U.S.C. § 1397bb(b); 42 C.F.R. § 457.320(a). This allows the states to determine how to define family income. 42 C.F.R. § 457.10 ("Family income means income as determined by the State for a family as defined by the State.") (emphasis added); see also 42 U.S.C. § 1397bb(b)(1) (Requiring that SCHIP State Plans include "a description of the standards used to determine the eligibility of targeted low-income children for child health assistance under the plan [which standards] include (to the extent consistent with this subchapter) those relating to [among other elements] income and resources ") HHS Secretary Michael O. Leavitt has acknowledged that this flexibility allows states to "effectively raise the income eligibility threshold." Declaration of Roger Gantz ("Gantz Decl."), Ex. C. The regulations state that "[w]ithin broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures." 42 C.F.R. § 457.1.

In general, the SCHIP statute permits a state to cover a child who is either (a) a "low income

child" or (b) a child whose family income, "as determined under the State child health plan," exceeds, but is no more than 50 percentage points above, the state's Medicaid eligibility standard. 42 U.S.C. § 1397jj(b). A "low income child" is in turn one "whose family income is at or below 200 percent of the poverty line for a family of the size involved." 42 U.S.C. § 1397jj(c)(4). As indicated in 42 U.S.C. § 1397jj(c)(5) and by reference in the Community Service Block Grant Act, 42 U.S.C. § 9902(2), the "poverty line" refers to the figures annually updated by Defendant in January or February of each year in the Federal Register. Although Defendant refers to them officially as "poverty guidelines," they are commonly referred to by both federal and state agencies and in the literature as the "federal poverty level" (FPL), and for any year they are the same throughout the contiguous 48 states and the District of Columbia, with separate guidelines only for Hawaii and Alaska. Arnold Decl. ¶ 5. For 2007 the FPL was fixed by Defendant for a family of three at \$17,170 and for a family of four at \$20,650. 72 Fed. Reg. 3147. In January of 2008, these figures were increased to \$17,600 and \$21,200 respectively. 73 Fed. Reg. 3971.

Defendant, through its Center for Medicare & Medicaid Services ("CMS"), has adopted regulations to implement SCHIP. 42 C.F.R. pt. 457. The regulations contain various reporting requirements so that Defendant can determine whether the state plans "substantially comply with the requirements" of Title XXI. 42 U.S.C. § 1397ff(c)(1). The Federal government reimburses participating states for a share of their expenditures in providing health coverage under an approved plan, with each state having a maximum limit on the amount of matching funds it can receive. To be eligible for matching funds under SCHIP, a state must submit a state child health plan for approval by CMS. Arnold Decl. ¶ 4. A state may amend its approved state child health plan in whole or in part at any time by submitting a state plan amendment to Defendant for approval. *Id*.

Before enrolling a child in its SCHIP program, states screen for eligibility for Medicaid. 42 C.F.R. § 457.350. Only children who are not eligible for Medicaid can be enrolled in the SCHIP program. *Id*.

Many states, including the State Plaintiffs, have for many years utilized income "disregards," *i.e.*, excluding certain elements of gross family income, when determining whether applicants meet SCHIP income eligibility standards. Arnold Decl. ¶ 7; Gantz Decl. ¶ 27; Tucker Decl. ¶ 8. This mechanism allows states to offer coverage through SCHIP to a broader segment of the population than would be the case if they were required to consider only applicants' gross income, without accounting for expenditures such as child care, certain work-related expenses, variances in the cost of living, and other expenses that make it impractical, if not impossible, for many working families to afford private health insurance. States have been utilizing this "disregard" procedure with Defendant's knowledge and approval since the initial enactment of SCHIP. Mann Decl. ¶ 8. Currently, Defendant has approved 14 states' SCHIP programs covering children at income levels above 250% of FPL. Mann Decl. ¶ 15 and Ex. C.

In order to ensure that state benefits do not substitute for other sources of health coverage, state health plans must describe "reasonable procedures" to prevent such substitution. 42 C.F.R. § 805. Consistent with the approach to maximize the states' flexibility, Defendant determined in promulgating the initial regulations to implement SCHIP shortly after its enactment that it did not have the legal authority to mandate states to adopt any particular substitution-prevention procedure. Mann Decl. ¶ 12; 64 Fed. Reg. 60922 (Nov. 8, 1999). Different states have adopted different procedures, such as waiting periods of various lengths, cost-sharing requirements, monitoring health insurance status at the time of application, verifying family insurance status through databases, and

preventing employers from changing dependent coverage policies that would favor a shift to public coverage. Mann Decl. ¶¶ 19-21; Arnold Decl. ¶ 16. Before the directive of August 17, 2007, Defendant had never disapproved a state plan because of insufficient substitution-prevention strategies. Mann Decl. ¶ 22.

SCHIP allows states, if they choose, to impose cost sharing requirements on families as a disincentive to forgoing private coverage. Mann Decl. ¶ 9. As of January 2008, 34 states charge premiums, ranging from \$50 per annum in Texas to \$3000 per annum in Tennessee for a family with two children. Mann Decl. ¶ 17 and Ex. D. Before issuing its directive of August 17, 2007, Defendant had never imposed any cost-sharing requirement as a condition for approval of a state plan. Mann Decl. ¶ 18.

The Plaintiff States' SCHIP Programs

i. New York's SCHIP Plan

New York first enacted Child Health Plus ("CHPlus") in 1991. Arnold Decl. ¶ 6. CHPlus became a federally approved SCHIP plan in 1998. *Id.* As of August 2007, CHPlus had enrolled nearly 400,000 children. *Id.*

With Defendant's approval, CHPlus has utilized certain income disregards to provide coverage to children with gross family income at or below 250% of FPL since July 1, 2000. Arnold Decl. ¶ 7; N.Y. McKinney's Pub. Health Law § 2511(2)(a)(ii). Because children whose family incomes are below 200% of FPL for children under age one, 133% for children one through five, and 100% for children six through eighteen qualify for Medicaid in New York, 97% of all enrolled children in either program are from families below 200% of FPL. Arnold Decl. ¶ 8.

Through these programs, New York reduced the number of uninsured children in the State

by 41% from 1997 to 2006. Arnold Decl. \P 9. As a result, the proportion of enrollees with a regular source of health care increased from 86% to 97%, the proportion of children receiving preventative health-care visits increased from 74% to 82%, and the unmet health-care needs of these children decreased by more than one-third. *Id.* The long-term uninsured and lowest-income children demonstrated the most dramatic gains after enrollment. *Id.*

In early 2007, New York by statute extended eligibility for CHPlus to uninsured children whose families' gross incomes are at or below 400% of FPL, contingent on federal financial participation. Arnold Decl. ¶ 10. New York submitted a state plan amendment to Defendant on or about April 12, 2007 ("SPA #10"). *Id*.

New York expanded its program because the fastest growing group of uninsured children in New York was the group between 250% and 400% of FPL. Arnold Decl. ¶ 12. Also, New York has one of the highest costs of living in the country, particularly in the downstate counties. Arnold Decl. ¶ 13-14. This expansion primarily relied on income disregards similar to those used by other states, and approved by Defendant, to provide coverage for children in families above 200% of FPL. Arnold Decl. ¶ 11. Coverage was not free; premiums rose with family income. *Id.* This premium is intended to help prevent substitution for other available health coverage. Arnold Decl. ¶ 16. To that end, the expansion plan will also implement a required six-month period of uninsurance, subject to certain exceptions beyond the family's control. *Id.* As noted, New York has not found substitution to be a problem; only 1.3% of new CHPlus enrollees have dropped insurance from group health plans. *Id.*

ii. Washington's SCHIP Program

Washington's SCHIP program was created following the enactment of Wash. Laws of 1999, ch. 370, which authorized the Washington Department of Social and Health Services ("DSHS") to create the program consistent with Title XXI of the Social Security Act. Gantz Decl. ¶ 6. The program began on February 1, 2000, after Washington received federal approval of its child health plan. Gantz Decl. ¶ 6. As of April 2008, approximately 13,000 children up to age 19 were enrolled in SCHIP. Gantz Decl. ¶ 6. Washington's plan has provided coverage to children up to age 19 whose families' income is between 200 to 250% of the FPL. Gantz Decl. ¶ 6. Coverage costs \$15 a month per child, with a family cap of \$45 per month. Gantz Decl. ¶ 6. Under Washington's state SCHIP plan, children who are eligible for Medicaid or who have any creditable health coverage are ineligible for SCHIP. Gantz Decl. ¶ 6. Between 2000 and 2006, Washington reduced the number of uninsured children in the State by 25% through implementation of its SCHIP program. Gantz Decl. ¶ 6. Washington has never utilized its share of federal funds allotted for SCHIP and in fact has returned more than \$125 million that it was unable to use. Gantz Decl. ¶ 7.

In 2007, the Washington Legislature enacted Wash. Laws of 2007, ch. 5, which authorized expansion of Washington's SCHIP program to include children from families whose income does not exceed 300% of the FPL, effective January 1, 2009. Gantz Decl. ¶ 8. DSHS has begun planning and outreach efforts necessary to comply with this legislative directive. Gantz Decl. ¶ 12. Implementing the law will also require approval of a State Plan amendment by Defendant and modification of Washington's eligibility regulations through the State rule-making process. Gantz Decl. ¶ 13.

Under the legislation to expand coverage, Washington expects to enroll approximately 3,000

low-income children in families with incomes above 250% of the federal poverty level by July 2009 and 8,000 by June of 2010. Gantz Decl. ¶ 8. Experience in other states demonstrates that similar expansions have also had the desirable effect of increasing enrollment among children already eligible for, but not currently enrolled in, either Medicaid or SCHIP, and this is also a substantial goal of the SCHIP program. Gantz Decl. ¶ 8; Arnold Decl. ¶ 23(c).

Washington's expanded SCHIP program will employ several strategies to minimize substitution of SCHIP coverage for available private coverage: (1) families will be required to disclose existing employer-based health insurance coverage on a SCHIP application under penalty of perjury, and children with such existing coverage will not be eligible for SCHIP coverage; (2) families will be required to enroll their children in available employer-sponsored health care when it is cost-effective for the State to contribute to the cost of such care rather than enrolling the children in the SCHIP program; (3) employer-sponsored plans will be required to enroll such children regardless of otherwise applicable enrollment limitations; (4) children from families whose incomes are greater than 250% of the FPL and who drop employer-based health insurance coverage to obtain SCHIP coverage will have a four-month waiting period before they can be enrolled in SCHIP, with limited exceptions; and (5) families will pay a monthly premium toward the cost of their coverage based on a sliding scale. Gantz Decl. ¶ 11.

iii. Maryland's SCHIP Program

Maryland created MCHP as a Medicaid expansion program in 1998. Declaration of Susan J. Tucker ("Tucker Decl.") ¶ 4. MCHP provides access to Medicaid services for eligible children under age 19 whose family income is below 200% of FPL. *Id.* Since July 1, 2001, MCHP has provided access to health insurance for children whose families' income are between 200% and

300% of FPL. Tucker Decl. ¶ 5. Children whose family income lies between 200% and 250% of FPL pay a premium of 2% of family income for a two-person household of 200% of FPL. *Id.* Children whose family income lies between 250% and 300% of FPL pay a premium of 2% of family income for a two-person household of 250% of FPL. *Id.*

Part of the 2001 legislation amended the MCHP program to create a stand-alone SCHIP component for the MCHP premium population, *i.e.*, between 200% and 300% of FPL. Tucker Decl. ¶¶ 5, 10. Upon Defendant's recommendation, Maryland amended its program in 2007 so that MCHP would once again be a Medicaid expansion program. Tucker Decl. ¶¶ 8, 10. As of January 2008, Maryland serves 82,703 children with family incomes too high for Medicaid but no greater than 185% of FPL and 9,449 children with family incomes between 185% and 200% of FPL in the free MCHP program. Tucker Decl. ¶ 9. As of March 2008, Maryland has 11,588 children with family incomes between 200% and 300% enrolled in MCHP premium. Tucker Decl. ¶ 9.

To prevent substitution for available private coverage, Maryland declares ineligible any applicant with benefits under an employer-sponsored health benefit plan with dependent coverage or under health insurance coverage. Tucker Decl. ¶11. Children of state employees with access to coverage under a state health benefit plan are likewise ineligible unless the state's contribution toward the cost of dependent coverage for the child is \$10 per month or less. *Id.* Maryland imposes a six-month waiting period before MCHP enrollment for applicants who voluntarily terminate coverage under an employer-sponsored health benefit plan. Tucker Decl. ¶ 11. Maryland also screens MCHP applicants and enrollees and monitors the extent of crowd-out. Tucker Decl. ¶¶ 12, 13. In six years of such monitoring, Maryland has never detected a problem that would necessitate additional crowd-out strategies. Tucker Decl ¶ 13.

From July 2001 to June 2003, Maryland offered an employer-sponsored insurance option that contributed payments to private health insurance plans rather than substituting public coverage. Tucker Decl. ¶¶ 5, 6, 14. When Defendant recommended that Maryland amend MCHP in 2007, Defendant did not recommend that Maryland revive this option or otherwise strengthen crowd-out-prevention measures. Tucker Decl. ¶ 14.

iv. Illinois's SCHIP Program

Illinois enacted its Children's Health Insurance Program Act ("CHIP") in 1998. 215 ILCS 106/1. Illinois subsequently expanded CHIP in the Covering All Kids Health Insurance Act in 2005. 215 ILCS 170/1. CHIP covers children whose family income is below 200% of FPL. 215 ILCS 106/20(a)(2).

Children whose family income is above 150% of FPL must pay premiums for CHIP coverage. Premiums range from \$15 per month for a single child to \$40 per month for five children or more. 215 ILCS 106/30(a)(2).

The August 17 Letter

On August 17, 2007, Defendant sent a letter to all state SCHIP directors. The August 17 Letter imposed new rules, which it explicitly described as "requirements," to prevent crowd-out and to limit SCHIP expansion. Arnold Decl., Ex. 9. With respect to crowd-out measures, the August 17 Letter required all states to employ all of the following crowd-out-prevention strategies:

- a state plan must charge premiums of at least 5% of family income or at least as much as competing private plans, within 1% of family income;
- a state must establish a minimum of a one-year period of uninsurance;
- monitoring and verification must include information regarding coverage provided by a noncustodial parent.

Arnold Decl., Ex. 9.

The August 17 letter further required certain assurances of outcomes of the states' outreach procedures:

- at least 95% enrollment of children below 200% of FPL
- no decrease by more than two percentage points of the number of target-population children insured through private employers
- monthly reports of data relating to crowd-out requirements.

Id.

Since the August 17 Letter, Defendant has instructed states via informal telephone conversations that these requirements are mandatory and that states that did not comply with those requirements would face compliance proceedings. Arnold Decl. ¶ 20; Declaration of Kevin Cornell ("Cornell Decl.") ¶¶ 4, 5; Tucker Decl. ¶ 17. Defendant also sent letters and e-mails to SCHIP directors describing the "required crowd-out strategies and assurances" of the August 17 Letter. Cornell Decl., Ex. A; Gantz Decl., Ex. B; Tucker Decl., Ex. 3.

Defendant Disapproves New York Plan Based on the Requirements of the August 17 Letter.

After receiving the August 17 Letter and learning that the requirements were mandatory, New York submitted written responses to Defendant's questions and several proposed adjustments to SPA #10 designed to accommodate Defendant's concerns without sacrificing the plan's objectives. Arnold Decl. ¶ 20. In response, Defendant, applying criteria first set forth in the August 17 Letter, disapproved SPA #10 on the grounds that SPA #10 had failed to provide assurances that New York had enrolled at least 95% of children under 200% of FPL, failed to include a one-year uninsurance requirement, and proposed cost-sharing premiums that would be lower than 5% of family income

and lower than those of competing plans by more than 1% of family income. Arnold Decl. \P 21. This disapproval stated that it was "consistent with the August 17, 2007 letter to State Health Officials." Arnold Decl. \P 21 and Ex. 10.

By letter dated October 31, 2007, New York requested reconsideration of Defendant's disapproval on the grounds that the sole basis for disapproval was the failure to meet new and improper requirements set forth in the August 17 Letter. Arnold Decl. ¶22 and Ex. 11. This request triggered an administrative proceeding, but in a letter dated November 30, 2007, Defendant reframed the issues to be determined at the reconsideration hearing in that proceeding with no mention of whether Defendant could legally require the new mandates of the August 17 Letter. Arnold Decl. ¶22 and Ex. 12. Defendant published a Notice of Hearing in the Federal Register framing the issues as Defendant had defined them in its response to New York's request for reconsideration. 72 Fed. Reg. 68888.

In April 2008, in the absence of federal SCHIP funding, the New York Legislature was required to allocate \$118 million in State funds to finance the planned expansion of CHPlus. Arnold Decl. ¶ 25. The expansion will be effective September 2008, but not September 2007 as originally anticipated. *Id.* New York has estimated that approximately 72,000 children will ultimately receive health coverage under the expansion. *Id.*

Other Effects of the August 17 Letter

Defendant has applied the requirements of the August 17 Letter to other states. Before the August 17 Letter, Pennsylvania successfully expanded its SCHIP program to 300% of FPL with a six-month uninsurance period for the expansion group, with exceptions for children under two whose parents lost their jobs. Mann Decl. ¶ 24. Louisiana, by contrast, which submitted its SCHIP

expansion proposal on September 5, 2007, was not permitted to expand its SCHIP program beyond 250% of FPL. Mann Decl. ¶ 26. Following the August 17 Letter, nine other states have sought federal approval of SCHIP expansions up to 300% of FPL, but no such expansions have received approval. Mann Decl. ¶ 27. At least 14 states whose SCHIP programs cover children above 250% of FPL, including Pennsylvania, currently face the threat of a compliance proceeding. Mann Decl. ¶ 28.

ARGUMENT

I. THIS COURT HAS SUBJECT-MATTER JURISDICTION OVER THIS ACTION.

Defendant argues that this Court should not hear this case, either because the case is unripe or because Plaintiffs must seek review elsewhere. Def. Mem., at 13-33. On the contrary, this Court does have jurisdiction, and this case is currently ripe for exercise of that jurisdiction.

A. This Dispute Is Ripe for Judicial Resolution.

The rationale of the ripeness doctrine is to prevent courts from "entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from interference until an administrative decision has been formalized and its effects felt in a concrete way." *Abbott Laboratories v. Gardner*, 387 U.S. 136, 148 (1967). A court must therefore determine "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 149. The "ripeness" doctrine arises from overlapping considerations of Article III limitations on judicial power and prudential reasons for refusing to exercise jurisdiction. *Ehrenfeld v. Mahfouz*, 489 F.3d 542, 545-6 (2d Cir. 2007). Constitutional ripeness requires a "concrete dispute affecting cognizable current concerns of the parties," whereas prudential ripeness precludes a case that "would be better decided later" *Id.* at 546. *See also Simmonds v. I.N.S.*, 326

F.3d 351, 357-58 (2d Cir. 2003).

An administrative decision is constitutionally fit for judicial review when its effects have been "felt in a concrete way by the challenging parties." *Amer. Acad. of Religion v. Chertoff,* 463 F. Supp.2d 400, 413 (S.D.N.Y. 2006) (Crotty, J.) (quoting Abbott Labs, 387 U.S. at 148-49); accord *Thomas v. Union Carbide Agric. Prods. Co., Inc.,* 473 U.S. 568, 581 (1985). The courts in this circuit have sometimes looked to a variety of factors in determining whether a case is prudentially ripe for determination, such as (1) whether the agency action is likely to have an immediate and substantial impact upon the complaining party, (2) whether the agency action is final, (3) whether the issue is more legal or factual in nature, (4) whether review would delay or impede effective enforcement of the relevant administrative scheme, and (5) whether the court has an adequate factual record. *Able v. U.S.,* 88 F.3d 1280, 1289-90 (2d Cir. 1996); see also Occidental Chemical Corp. v. F.E.R.C., 869 F.2d 127, 129 (2d Cir. 1989); Aquavella v. Richardson, 437 F.2d 397, 403-04 (2d Cir. 1971); N.Y. Mercantile Exchange v. Commodity Futures Trading Comm'n, 828 F. Supp. 186, 190 (S.D.N.Y. 1993). Here, all of these factors weigh in favor of finding that this case is ripe.

1. The August 17 Letter Has Had an Immediate, Substantial and Concrete Impact Upon the Plaintiff States.

The effects of the August 17 Letter are unquestionably being concretely felt now. The particular effects on the four Plaintiff States are described in the declarations submitted by each. New York has seen its plan amendment disapproved on the grounds that it did not meet the August 17 Letter's criteria for approval. Arnold Decl., Ex. 10. Because New York cannot comply with these criteria, it is being deprived of federal funding in an amount estimated to be approximately \$118 million and has been compelled to allocate state monies to replace federal funding to

implement its SCHIP program. Arnold Decl. ¶¶ 23, 25. Not only has health insurance coverage been delayed by at least a year for approximately 72,000 children in New York, but if New York funds what would have been the federal share of its expanded SCHIP program out of state-only monies, as its Legislature has expressed its intention to do in its new budget, it must necessarily divert those funds from other state programs. Arnold Decl. ¶ 25.

The other Plaintiff States are also seriously affected. Maryland, which already had an approved SCHIP program that includes children in families up to 300 percent of FPL, has been told by Defendant that it must bring its plan into compliance with the August 17 Letter's requirements by August 16, 2008, and that although it is not required to remove children above 250 percent of FPL from its rolls before that date, thereafter the restrictions of the August 17 Letter will apply to current enrollees. Tucker Decl. ¶ 16 and Ex. 3. Communications between Maryland and Defendant have left no doubt that the August 17 directives are mandatory and that Maryland must retool its existing SCHIP program to come into compliance with the August 17 criteria: it must double its current (and Defendant-approved) waiting period; raise the charges to families seeking SCHIP coverage; effect some unspecified alteration in private plan coverage (which may implicate ERISA preemption issues); forgo coverage unless it demonstrates a 95% coverage rate for families at or below 200% of FPL, which apparently has not been accomplished by any state; and forgo coverage absent assurance in a manner yet to be determined that there has not been more than a 2% decrease in private coverage. Tucker Decl. ¶¶ 17-22.

Washington has enacted legislation that authorizes expansion of its SCHIP program to cover children with family income up to 300 percent of FPL (in reliance on Defendant's past approvals of such coverage by other states). It estimates that approximately 2,700 children who would have

become insured under the new plan will remain uninsured because of Defendant's new rules in its August 17 Letter and that an additional approximately 1,800 children who are now covered under Washington's plan may lose their health care coverage. Gantz Decl. ¶¶ 16, 28. Plaintiffs' claims are thus constitutionally ripe and also satisfy an important factor in the prudential ripeness inquiry.

Defendant argues that this impact does not constitute "cognizable hardship" because Plaintiffs' currently-approved plans (other than Maryland's) do not now insure children above 250% FPL¹ and these Plaintiffs should complete the plan amendment process, including administrative hearings and the judicial review permitted by the statute. Def. Mem., at 22-23. Citing Simmonds, 326 F.3d at 360, it contends that the August 17 Letter does not create a "direct and immediate dilemma" for those Plaintiffs. In Simmonds, the court found unripe a habeas corpus petition against an order of removal from the country by a prisoner serving a life sentence in state prison because it was uncertain when, if ever, the habeas corpus would be necessary. Id. Here, however, Plaintiffs are now subject to mandatory new rules that present them with a costly choice: to comply with Defendant's new and draconian rules or forfeit federal funding for a significant population of children. Indeed, pursuant to 42 C.F.R 457.204(d)(3)(ii), the noncompliance of a state's plan can be the basis of the withholding of all or part of its federal SCHIP payments, and "noncompliance" is defined to include "the failure of the State to change its approved plan to conform to a new Federal requirement for approval of state plans." 42 C.F.R. 457.204(a)(2)(b). This case is thus similar to Abbott Labs, perhaps the most widely cited case on ripeness, in which the Supreme Court held that

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¹ Defendant's Memorandum is incorrect in this regard. After deductions and disregards, Washington also covers children with gross family income above 250 percent of the FPL. Gantz Decl. ¶ 27.

² This argument presupposes that the administrative process can grant adequate relief to Plaintiff States. As demonstrated in Section I.C, *infra*, it cannot.

the impact of the challenged agency action was sufficiently direct and immediate because it placed the regulated parties in the dilemma of either complying with the requirement, at great expense, or risking serious penalties. 387 U.S. at 152; see also Diamond Shamrock Corp. v. Costle, 580 F.2d 670, 673 (D.C. Cir. 1978). As the Supreme Court recently reaffirmed, "where threatened action by government is concerned, we do not require a plaintiff to expose himself to liability before bringing a suit to challenge the basis for the threat." Medimmune, Inc. v. Genentech, Inc., 127 S.Ct. 764, 772 (2007); see also Union Carbide, 473 U.S. at 581 ("One does not have to await the consummation of threatened injury to obtain preventive relief. If the injury is certainly impending, that is enough") (internal citations omitted); Cf. Steffel v. Thompson, 415 U.S. 452, 459 (1974) ("it is not necessary that petitioner first expose himself to actual arrest or prosecution to be entitled to challenge a statute that he claims deters the exercise of his constitutional rights").

With respect to Plaintiff Maryland, which already covers children above 250 percent of FPL with Defendant's approval, Defendant's Memorandum of Law contends that "Defendant has not addressed whether it will apply the review strategy in the SHO Letter, or any similar review strategy, to Medicaid expansions" (Maryland's SCHIP plan is currently structured as an expansion of its Medicaid program). Def. Mem., at 23. But this assertion by its counsel is flatly contradicted by the January 28, 2008 letter sent by Defendant to the Maryland SCHIP Director, in which Defendant's Acting Director expressly advised Maryland, as a state that currently provides coverage to children over 250 percent of FPL, that it has "12 months or until August 16, 2008, to come into compliance with the required crowd-out strategies and assurances laid out in the August 17th SHO for new enrollees" and that Defendant intended to "work cooperatively" with Maryland so that it would be able to enroll children in higher income families "if the reasonable standards of the August 17th

guidance are met" Tucker Decl., Ex. 3. Moreover, in contradiction to the statement made on pages 24-25 of Defendant's Memorandum of Law, Defendant has told Maryland officials that commencing August 16, 2008, the restrictions of the Letter would apply to *current*, in addition to new, enrollees. Tucker Decl. ¶ 16. In addition, in any state like Maryland or Washington that covers children in the over-250-percent-of-FPL-group, if such a child leaves the SCHIP program (for example, because his or her parent obtains a job with health coverage), he or she could not return to the program if the parent should lose the job or the coverage. *See* Gantz Decl. ¶¶ 29-30.

The Plaintiff States are suffering hardship and will continue to suffer such hardship so long as Defendant relies on the criteria in the August 17 Letter for approval or disapproval of SCHIP plans. These are concrete effects, which render this dispute both constitutionally and prudentially ripe. *See Amer. Acad. of Religion*, 463 F. Supp.2d at 413-14 (government exclusion of foreign visitor did not require official decision to render dispute ripe).

2. Issuance of the August 17 Letter Constituted Final Action.

Agency action is final when it (1) consummates the agency's decision-making process, and (2) has determined rights or obligations or caused legal consequences to flow. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). Here, the facts satisfy both criteria.

The August 17 Letter did not request comment or put forth tentative guidelines. It instructed states to follow explicit and detailed criteria. Specifically, the August 17 Letter directed (a) that procedures adopted by the states to prevent crowd-out "should include" all five strategies listed; (b) that cost-sharing under the state plan "must not" be more favorable to that of the public plan by more than one percent of the family's income; (c) that the state "must" establish a minimum of a one year waiting period of uninsurance; (d) that monitoring "must" include certain information; (e) that

Defendant "will ask" for the required "assurances" that the state has enrolled at least 95 percent of children below 200 percent of FPL, that the number of children in the target population who are insured by private employers had not decreased by more than 2 percent, and that the state was current on all reporting requirements; and (f) that "we expect" affected states to amend their plans "in accordance with this review strategy" within 12 months, or Defendant "may pursue corrective action." Arnold Decl., Ex. 9. These are not tentative words. They express a final decision, an expectation that states will comply with that decision or suffer the legal consequences that will flow from failing to conform to the August 17 Letter. The subsequent disapproval of the New York Plan Amendment on the grounds specifically enumerated in the August 17 Letter demonstrates that this threat was not idle or hypothetical.

Defendant argues that the August 17 Letter does not constitute final action because it "has no binding effect by itself, but only serves to guide future decision-making" and that any binding effect could occur "only through a plan amendment proceeding or compliance proceeding." Def. Mem., at 15. Defendant said precisely the opposite in a letter to SCHIP directors in states that already covered children in families above 250 percent of FPL dated January 28, 2008, in which Defendant described the "required crowd-out strategies and assurances laid out in the August 17th SHO for new enrollees." Tucker Decl., Ex. 3; Gantz Decl. Ex. B (emphasis added).

Defendant's attempt to interpret the words "we will expect" and "we will ask" as tentative predictions of possible future positions is, of course, absurd. Its use of the word "expect" expresses a requirement, consistent with the word's definition: "to look for with reason or justification: we expect obedience." Random House Dictionary, at 464 (rev. ed. 1984). The August 17 Letter was not an expression of hope for the future; it was a mandate. See Abbott Labs, in which the Supreme

Court held the impact of the regulations in question sufficiently direct and immediate to support ripeness because, *inter alia*, the agency's counsel had represented "that immediate compliance with their terms was *expected*." 387 U.S. at 152 (emphasis added).

New York's experience also directly contradicts Defendant's contention. When New York sought approval for its Plan Amendment, Defendant denied the request specifically on the very grounds that Defendant now claims to be non-binding. Defendant denied New York's request not on general grounds of effectiveness or efficiency, but specifically because New York "failed to provide assurances that the State has enrolled at least 95 percent of the children . . . below 200 percent of the FPL." Arnold Decl., Ex. 10. Defendant further relied not on general grounds of a lack of "reasonable procedures" to prevent crowd-out, but specifically on the grounds that New York's proposal did not comport with the requirements set forth for the first time in the August 17 Directive, namely that it did "not include procedures to prevent such substitution that include a 1-year period of uninsurance for populations over 250 percent of the FPL." *Id*.

Defendant further argues that Plaintiffs are "free to challenge the policies outlined in the SHO Letter during the administrative process, and the agency is free to depart from them." Def. Mem., at 16. However, Defendant never offered New York any opportunity either to provide assurances that it has expanded the provision of health assistance to uninsured children effectively and efficiently in any manner other than guaranteeing 95% enrollment of the children below 200% FPL, or to demonstrate that it utilized different reasonable procedures from those upon which Defendant insisted to prevent crowd-out. Instead, Defendant disapproved New York's plan by application of the August 17 criteria.

New York is currently in the middle of that administrative process, and Defendant's statements in that process also contradict its assertion here. By letter dated November 30, 2007, Defendant delineated the issues that will be subject to administrative review. Arnold Decl., Ex. 12. It completely rejected New York's request that the propriety and legality of the August 17 Letter directives be considered at the hearing, thus limiting the administrative hearing to matters other than those posed by the August 17 directives. Arnold Decl., Exs. 11, 12. These statements suggest an intention to disregard any challenges to the policies contained in the August 17 Letter. Defendant cannot take one position in the administrative process and the opposite position here.

Defendant's communications with Maryland, with Washington, and with other states, in which it has sought a timetable for compliance with the August 17 Letter directives and expressed a willingness to discuss methods of compliance but has been unwilling to consider any change in the requirements of the August 17 Letter, provide conclusive evidence that it was intended as a final rule. Tucker Decl., Ex. 3 and ¶¶ 16-17; Cornell Decl. ¶¶ 4-6; Gantz Decl. ¶¶ 31-34 and Ex. B. "Though the agency has not dressed its decision with the conventional procedural accoutrements of finality, its own behavior thus belies the claim that its interpretation is not final." Whitman v. American Trucking Assns., 531 U.S. 457, 479 (2001). In the Whitman case, in light of the agency's refusal to reconsider its "interpretation" in response to disappointed commenters, the Supreme Court had "little trouble concluding that this constitutes final agency action subject to review under § 307 [of the APA]." Id. at 478.

3. The Issues Are Purely Legal.

The first issue that Plaintiff States have asked this Court to decide in this action, and upon which they seek summary judgment, is whether the August 17 Letter directives constituted legislative rules and whether Defendant followed APA procedures in promulgating them. This depends entirely on this Court's interpretation of APA procedures and the question of whether the directives promulgated constitute "rules" as defined in the APA. Whether a federal document is a "rule" or merely "guidance" is a legal question. *Gen. Elec. Co. v. E.P.A.*, 290 F.3d 377, 380 (D.C. Cir. 2002). Defendant has not argued otherwise.

The second issue, which is not part of Plaintiffs' motion for summary judgment but may be an issue for discovery and trial, depending on the Court's ruling on Plaintiffs' summary-judgment motion, is whether the rules enumerated in the August 17 Letter are arbitrary, capricious, and contrary to law. An agency rule is arbitrary and capricious when the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Manufacturers Ass'n of the U.S., Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983). This issue also will depend not on applications to particular state plans, but rather on a judgment as to whether the rules are legally consistent with Title XXI. The statutory authority of an agency is purely a legal question. *Aquavella*, 437 F.2d at 404. Although there may be some factual debate with respect to this issue, including possible disagreement of expert witnesses, the facts at issue would not be of the kind that would be clarified by a more developed administrative record, as opposed to discovery in the action. Obviously, the existence of issues of

fact does not automatically make an action unripe, or there would be no use for discovery or trials.

4. Review Would Neither Impede Nor Delay Enforcement of SCHIP Rules.

The Defendant has already issued the August 17 Letter and is already insisting on enforcement of its terms. This Court will not prevent Defendant from continuing to do so by reviewing this case, nor will this Court cause any harm that would require repair if this Court ultimately were to rule in favor of Defendant. Nor will any decision of this Court prevent Defendant from continuing its normal review of state plans. Defendant has not argued otherwise. Thus, this factor weighs in favor of finding that this case is ripe. *See Whitman*, 531 U.S. at 479 (review would not interfere with EPA's implementation policy).

5. This Court Has an Adequate Factual Record.

As demonstrated above, the issue before this Court is purely legal. Further fact-finding would have no effect on the issue of whether the August 17 Letter issued new rules in contravention of the APA and whether these rules contravene the Social Security Act. Such issues are "presumptively reviewable." *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Eng'rs*, 417 F.3d 1272, 1282 (D.C. Cir. 2005). They do not turn on particular applications at administrative hearings.

Defendant argues that this Court should await further factual development before determining whether the requirements of the August 17 Letter are contrary to law. Def. Mem., at 18. It argues that facts may show that the 95%-enrollment requirement and the 5% income cap are reasonable. Def. Mem., at 19-20. Defendant is free to argue that these requirements are reasonable, but that is not the issue on the Plaintiff States' present motion for summary judgment. It has no bearing on whether the directives were properly issued and accord with the law.

Defendant also argues that the reasonableness of the 12-month-uninsurance requirement

depends on whether a shorter requirement has "proven sufficiently effective at preventing crowdout." Def. Mem., at 19. This argument assumes that Plaintiff States will have an opportunity to
make such a showing at an administrative hearing, which in turn assumes that the requirement is not
a rule and that Defendant is prepared to consider the effectiveness of a shorter period in the
administrative hearing. But the issue that Plaintiffs are now asking this Court to decide is not
whether the Defendant is right or wrong in its policy decision, but rather whether it has improperly
made a binding rule based on that policy without following required procedures. Defendant cannot
obtain dismissal based on the assumption that Plaintiffs' allegations that Defendant made such a rule
are incorrect.

B. The Statutory Review Scheme Does Not Preclude Plaintiffs From Seeking Pre-Enforcement Review of the Directives in the August 17 Letter.

Defendant argues that "the judicial review mechanism prescribed by the SCHIP statute provides the exclusive vehicle through which plaintiffs' claims may be litigated," and that this mechanism "grants a right to judicial review only where CMS has made a final determination that a state's plan or plan amendment does not meet the federal requirements," and "permits appeal only in federal appeals court." Def. Mem., at 26-27. Therefore, it contends, Plaintiffs "cannot circumvent" the statutory "exclusive *post*-enforcement review mechanism by bringing an action for *pre*-enforcement review in this Court." *Id.* at 28. This argument reflects both a distortion of the statutory provisions and a mischaracterization of Plaintiffs' claims.

The SCHIP statute, in 42 U.S.C. § 1397gg(e)(2), incorporates by reference the administrative and judicial review provisions applicable to Medicaid in 42 U.S.C. § 1316. The latter provision provides that "[w]henever a State plan is submitted to the Secretary by a State for approval . . . he

shall... make a determination as to whether it conforms to the requirements for approval under such title." 42 U.S.C. § 1316(a)(1). When a state is dissatisfied with that determination, it may seek administrative "reconsideration," and ultimately appellate-court review, of the determination as to whether its particular state plan conforms to federal requirements. 42 U.S.C. 1316(a)(2)-(3).

Defendant argues that if Congress specifies a forum for judicial review of "certain administrative action, that forum is presumed exclusive for that category of action." Def. Mem., at 27. However, the issues to be decided and the relief sought in this case are different from the issues and relief which are presented for administrative and judicial review in the reconsideration proceeding. Plaintiff States are not asking this Court to make any determinations about their particular respective SCHIP plans. Rather, Plaintiffs present a facial challenge to the new rules that Defendant illegally promulgated through its August 17 Letter, rules that offer states the Hobson's choice of either risking losing their federal funding or abandoning their plans or existing programs to cover children above 250 percent of FPL. As demonstrated in Point I.A.1, *supra*, the Plaintiff States (as well as other states similarly situated) are faced with this dilemma now, rather than at some future date after administrative hearings and judicial review are completed.

In *McNary v. Haitian Refugee Ctr.*, 498 U.S. 479 (1991), deportable aliens challenged the manner in which the Immigration and Naturalization Service (INS) administered determinations for Special Agricultural Worker status. Rejecting the INS's argument that § 210(e) of the Immigration and Nationality Act precluded jurisdiction, the Supreme Court held that the plaintiffs "do not challenge the merits of any individual status determination; rather . . . they contend that defendant's policies and practices in processing SAW applications deprive them of their statutory and constitutional rights." *Id.* at 490. Just as the review process in *McNary* applied to "a single act,"

rather than "general collateral challenges," the review process of 42 U.S.C. § 1316 applies only to the single act of a particular state plan, rather than the collateral challenge to the regulations according to which Defendant reviews such plans.

Similarly, the plaintiffs in *Bowen v. City of New York*, 476 U.S. 467 (1986), challenged "an unlawful, unpublished policy under which countless deserving claimants were denied benefits." *Id.* at 473. Because these claims were "collateral to the benefits that class members had presented administratively," and because the plaintiffs "neither sought nor were awarded benefits in the District Court," the case was "materially distinguishable from one in which the claimant sues in district court, alleging mere deviation from the applicable regulations in his particular administrative proceeding." *Id.* at 483-84. Plaintiff States here similarly do not seek approval of their respective state plans, but rather collaterally challenge the process by which Defendant reviews such plans. *See also Matthews v. Eldridge*, 424 U.S. 319, 331 (1976) (constitutional challenge to administrative procedures reviewing disability benefits was collateral to substantive claim of entitlement); *Skubel v. Fuoroli*, 113 F.3d 330, 334 (2d Cir. 1997) (failure to exhaust can be excused if claim is "collateral to a demand for benefits").

Defendant's reliance on *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200 (1994), is misplaced. The *Thunder Basin* Plaintiff sought review of a specific order of the Mine Safety and Health Administration (MSHA) to post in its coal mine work place the designations of two miner representatives by the union on the ground that it violated the employer's rights under the National Labor Relations Act. 510 U.S. at 204. The *Thunder Basin* court found that the Mine Act precluded district court jurisdiction over the pre-enforcement challenge because the statute itself "establishes a detailed structure for reviewing violations of 'any mandatory health or safety standard, rule, order,

or regulation promulgated' under the Act." *Id.* at 207 (citing 30 U.S.C. § 814(a)). It distinguished McNary on the grounds that unlike the Mine Act, the statute in that case did not provide for administrative review of "broad 'pattern and practice' challenges." *Id.* at 213-14. In the case at bar, however, § 1397gg(e)(2), incorporating § 1316, provides only for review of a particular state plan, not for the collateral review of HHS regulations that the Plaintiff States seek. Consequently, Thunder Basin is inapposite; McNary and Bowen control. The SCHIP statute does not preclude preenforcement review of these regulations. See also Nat'l Mining Ass'n v. Dept. of Labor, 292 F.3d 849, 856 (D.C. Cir. 2002) (holding that appellate review of administrative orders under Black Lung Benefits Act did not preclude jurisdiction under APA for review of regulations).

As the Supreme Court said in *Abbott Labs*, *supra*, "judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." 387 U.S. at 140; cf. Coit Independence Joint Venture v. Federal Savings and Loan Insurance Corporation, 489 U.S. 561, 579-80 (1989) (in absence of explicit statutory requirement of exhaustion of administrative remedies, court should not defer exercise of jurisdiction unless consistent with congressional intent). The "mere fact that some acts are made reviewable should not suffice to support an implication of exclusion as to others." Abbott Labs, 387 U.S. at 141; see also California v. Shalala, 166 F.3d 1019 (9th Cir. 1999) (court of appeals had no jurisdiction under statutory review procedure where statute omitted the category of state plan amendments involved, but petitioner would have a remedy in district court under the APA).³

³ Neither the SCHIP statute nor the Medicaid judicial review provisions that it incorporates by reference contains an express provision that the administrative and judicial remedies are exclusive. Congress knows how to make a remedy exclusive when it chooses to do so. See, e.g., Ruiz-Martinez v. Mukasey, 516 F.3d 102 (2d Cir. 2008), upholding the provision in the 2005 REAL ID Act that directed petitions for review of removal orders by the Board of Immigration Appeals to be the "sole and exclusive means for judicial review." 8 U.S.C. § 1252(a)(5).

C. The SCHIP Statute Does Not Provide an Adequate Alternative to APA Review.

Defendant argues that it has not waived sovereign immunity because the APA provides for judicial review only where no other remedy is available. Def. Mem., at 31. Defendant further argues that Plaintiff States can obtain judicial review of Defendant's illegally promulgated regulations through the administrative process. Def. Mem., at 32-33. As noted in Point I.B, *supra*, the administrative process that the SCHIP statute incorporates provides only for review of a particular adjudication of a state plan, and not of the regulations governing that adjudication. That *some* acts are reviewable in the statutory administrative procedure does not imply that the court should exclude the review of *other* acts. *Abbott Labs*, 387 U.S. at 141; *see also Gibson v. Berryhill*, 411 U.S. 564, 575 (1973) (alternative remedy was inadequate where plaintiff challenged adequacy of remedy). Thus, this Court should not forgo review of Defendant's illegally promulgated regulations merely because the SCHIP statute provides for review of the determination of a particular state's plan or plan amendment.

Even if the administrative process allowed review of Defendant's illegally promulgated regulations, such review does not preclude judicial review where the administrative body has predetermined the issues before it. *Gibson*, 411 U.S. at 578; *Houghton v. Shafer*, 392 U.S. 639, 640 (1968). Defendant has unequivocally declared that it will not review the legality of its regulations in the August 17 Letter. In its letter to New York and in its subsequent notice of hearing in the Federal Register, Defendant and its hearing officer reframed the issues in a way that does not present the validity of the August 17 Letter for decision. Arnold Decl. ¶ 22 and Ex. 12; 72 Fed. Reg. 68888. The August 17 Letter itself utilizes mandatory language, such as that competing private plans "*must* not be more favorable to the public plan by more than one percent," "the State *must* establish a

Page 40 of 58

minimum of a one year period of uninsurance," and "monitoring and verification *must* include . . . " (emphasis added). Consistent with that attitude, Defendant has repeatedly informed Plaintiff States that these requirements are mandatory and allow no exceptions. Arnold Decl. ¶¶ 20, 26; Cornell Decl. ¶ 5, 6 and Ex. A; Tucker Decl. Ex. ¶ 16-17. Thus, the alternate remedy Defendant suggests would be futile and does not preclude review by this Court. See Skubel, 113 F.3d at 334-35 (excusing plaintiff's failure to exhaust administrative remedies where letters from the agency indicated its unwillingness to change the regulation in question and pursuing the administrative remedy would be futile); see also Able, 88 F.3d at 1289.4

Document 30

II. PLAINTIFFS ARE ENTITLED TO A DECLARATORY JUDGMENT THAT THE AUGUST 17 LETTER IMPOSES INVALID MANDATES AND REQUIREMENTS.

Plaintiffs are entitled to summary judgment on two of the six grounds on which Plaintiffs have asked this Court for relief. First, the August 17 Letter imposes mandates and requirements not set forth in statute or codified regulations, and therefore under 45 C.F.R. § 92.11, Defendant cannot lawfully impose such requirements on participating states. Compl., Section V.A., ¶ 5. Second, the August 17 Letter failed to comply with the notice-and-comment requirements of the Administrative Procedure Act, 5 U.S.C. § 500 et seq. (The "APA") and thus constitutes invalid rule-making. Compl., Section V.A., ¶¶ 1, 2.

⁴ The administrative procedure contemplated by the SCHIP statute would be conducted by Defendant's Departmental Review Board. The present Secretary has recently proposed a new regulation (72 Fed. Reg. 73708, dated December 28, 2007) to insure that the Board not exercise too much independence in such proceedings by requiring it to follow "published guidance that is not inconsistent with applicable statutes and regulations" and to permit the Secretary to "correct ...deviations from published guidance."

A. State Programs Need Only Meet Requirements of Statutes or Codified Regulations.

Under Defendant's own rules, where a federal program such as SCHIP requires states to submit plans before receiving grants, the state plan need meet only those requirements that are in statutes or codified regulations. 45 C.F.R. § 92.11(b). The August 17 Letter imposes additional requirements, such as 95% participation of children below 200% of FPL, twelve-month waiting period, and others. Arnold Decl., Ex. 9. Defendant concedes that no statute or codified regulation contains these requirements. Def. Mem., at 33. Thus, Defendant cannot impose these requirements on the Plaintiff States. *See Morton v. Ruiz*, 415 U.S. 199, 235 (1974) (holding that BIA could not impose eligibility requirement found in BIA manual where requirement had not been published in Federal Register).

B. The Mandates and Requirements of Defendant's August 17 Letter Constitute Legislative Rules, Which May Be Adopted Only After Notice-and-Comment Rule-Making.

Under the APA, a federal agency can adopt legislative rules, *i.e.*, those that impose binding requirements on the regulated community, only after the agency has given notice of its intention to adopt rules and solicited comments from the regulated community and others. The agency seeking to adopt a rule must publish in the Federal Register and provide the public with an opportunity to comment. 5 U.S.C. § 553(b), (c); *see also Sweet v. Sheahan*, 235 F.3d 80, 90 (2nd Cir. 2000). Any rule that does not follow this process is invalid. 5 U.S.C. § 706(2)(D); *Chrysler Corp. v. Brown*, 441

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⁵Although rules relating to "public property, loan, grants, benefits, or contracts" are exempt from notice-and-comment requirements, Defendant has voluntarily adopted a policy of conducting rule-making consistent with APA requirements. 36 Fed. Reg. 2532 (Feb. 5, 1971). Courts have routinely enforced these policies on the logic that agencies must follow their own rules. See, e.g., Yesler Terrace Cmty. Council v. Cisneros, 37 F.3d 442, 447 (9th Cir. 1994) (HUD); Batterton v. Marshall, 648 F.2d 694, 700 (D.C. Cir. 1980) (Department of Labor); Rodway v. Dept. of Agriculture, 514 F.2d 809, 814 (D.C. Cir. 1975).

U.S. 281, 315-16 (1979).

Defendant does not dispute this basic tenet of administrative law. Defendant acknowledges that it issued the August 17 Letter without undertaking notice-and-comment procedures but claims that the August 17 Letter "qualifies as a general statement of policy or interpretive rule" under the criteria established in the case law. Def. Mem., at 35. This self-serving characterization "is obviously of little weight." *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320 (D.C. Cir. 1988). Defendant's past applications are what count. *Id*.

Although different courts have framed the distinction between legislative rules and general policy statements and interpretive rules in different ways, they have all focused on whether the agency's pronouncement imposes a legally binding norm upon regulated parties and limits the agency's own discretion. See American Mining Congress v. Mine Safety & Health Admin., 995 F.2d 1106, 1109 (D.C. Cir. 1993) (substantive rules "have the force and effect of law"); see also CropLife America v. E.P.A., 329 F.3d 876, 883 (D.C. Cir. 2003) (substantive rules "bind[] private parties or the agency itself with the 'force of law'" (internal quotation omitted)); Chamber of Commerce v. Dept. of Labor, 174 F.3d 206, 212 (D.C. Cir. 1999) (substantive rules "grant rights, impose obligations, or produce other significant effects on private interests . . . that agency rule is backed by the force of law suggests it is substantive"). Legislative rules have the "force and effect of law" and affect "individual rights and obligations." Chrysler, 441 U.S. at 301-02. General statements of policy and interpretive rules, by contrast, "do not have the force and effect of law." Id. at 302 (citing Attorney General's Manual on the Administrative Procedure Act (1947)). A general statement of policy "does not seek to impose or elaborate or interpret a legal norm. It merely represents an agency position with respect to how it will treat — typically enforce — the governing legal norm." Syncor Intern. Corp. v. Shalala, 127 F.3d 90, 94 (D.C. Cir. 1997); see also Chrysler, 441 U.S. at 302. An interpretive rule "typically reflects an agency's construction of a statute that has been entrusted to the agency to administer. The legal norm is one that Congress has devised; the agency does not purport to modify that norm, in other words, to engage in lawmaking." Syncor, 127 F.3d at 94; see also United States v. Yuzary, 55 F.3d 47 (2d Cir. 1995).

The Second Circuit has never adopted a comprehensive test to distinguish legislative rules from interpretive rules or mere policy guidance. However, it has noted that legislative rules "create new law, rights, or duties" and that such rules are intended to "bind members of the agency and the public." *Sweet v. Sheahan*, 235 F.3d 80, 91 (2d Cir. 2000). Here, the language of the August 17 Letter, Defendant's subsequent actions in treating the August 17 Letter as binding, and the significant alteration in the duties now imposed on the Plaintiff States all demonstrate that Defendant intended the August 17 Letter to be binding.

1. The Language of the August 17 Letter Demonstrates Defendant's Intent To Bind the States.

An agency's plain language is a strong indicator of the agency's intent to promulgate binding regulations. *Community Nutrition Inst. v. Young,* 818 F.2d 943, 947 (D.C. Cir. 1987). In *Community Nutrition,* the court invalidated the FDA standards establishing acceptable levels of food contamination because the language demonstrated that its requirements were "not musings about what the FDA might do in the future but rather [] set a precise level of . . . contamination that FDA has presently deemed permissible." *Id.* at 948. The court noted that the "so-called policy statement" would be "taken for what it is—a binding rule of substantive law." *Id. See also Alaska v. Dept. of Transp.*, 868 F.2d 441, 447 (D.C. Cir. 1989) (agency directive was found to be a legislative rule

subject to rule-making requirements where it employed mandatory language and required exceptions for deviation therefrom, thereby creating "bright-line tests to shape and channel agency enforcement").

The August 17 Letter employs mandatory language that demonstrates a present intent to bind states:

The cost-sharing requirement . . . *must* not be more favorable to the public plan by more than one percent of the family income . . .

(Emphasis added.)

The State *must* establish a minimum of a one-year period of uninsurance . . .

(Emphasis added)

Monitoring and verification *must* include information regarding coverage provided by a noncustodial parent.

(Emphasis added)

CMS will apply this review strategy to SCHIP state plans and section 1115 demonstration waivers

(Emphasis added.)

We expect affected States to amend their SCHIP state plan (or 1115 demonstration) in accordance with this review strategy within 12 months, or CMS may pursue corrective action.

(Emphasis added.)

Arnold Decl., Ex. 9.

2. Defendant's Conduct Demonstrates Its Intent To Treat the Requirements of the August 17 Letter as Binding Obligations.

If an agency treats a document "as controlling in the field, if it treats the document in the same manner as it treats a legislative rule, if it bases enforcement actions on the policies or interpretations formulated in the document, if it leads private parties or State permitting authorities to believe that it will declare permits invalid unless they comply with the terms of the document, then the agency's document is for all practical purposes binding." Appalachian Power Co. v. E.P.A., 208 F.3d 1015, 1021 (D.C. Cir. 2000). Defendant has made it clear at every available opportunity that it will require states to follow the strictures of the August 17 Letter. On January 29, 2008, CMS Director Dennis G. Smith's testimony before the House Energy & Commerce Subcommittee on Health acknowledged Defendant's expectation that states would "implement" the August 17 Letter. He also testified that the 95%-enrollment requirement "should be expected and demanded." One day before Director Smith's Congressional testimony, Susan Cuerdon, Acting Director of CMS's Family & Children's Health Program, sent a letter reminding states that they had 12 months "to come into compliance with the required crowd-out strategies laid out in the August 17th SHO [letter]" and pledging Defendant's cooperation to approve states' plan amendments "if the reasonable standards of the August 17th guidance are met." Gantz Decl., Ex. B; Tucker Decl., Ex. 3 (emphasis added).

Similarly, Defendant's conduct vis-à-vis the Plaintiff States demonstrates an intent to enforce the requirements of the August 17 Letter. For example, Defendant informed Washington State officials that it would not approve any SCHIP expansions that did not meet all of the requirements

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⁶Testimony of Dennis G. Smith, Director, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services, Before the House Energy & Commerce Subcommittee on Health, "Covering Uninsured Kids: Missed Opportunities for Moving Forward", January 29, 2008, available on HHS website at http://www.hhs.gov/asl/testify/2008/01/t20080129d.html (visited April 14, 2008).

of the August 17 Letter and that only the source of data would be open to negotiation. Cornell Decl. ¶ 5. Defendant immediately followed with an e-mail expressing interest in "establishing compliance with the August 17th SHO letter." Cornell Decl. ¶ 6 and Ex. A.

Defendant similarly treated the August 17 Letter as binding on New York. Before issuing the August 17 Letter, Defendant requested information on New York's SPA #10 merely to "clarify whether its proposed strategy will prevent substitution of coverage for children in families with income above 250 percent of the Federal Poverty Level (FPL) consistent with the requirements of Section 2102(b)(3)(C) and the applicable regulations at 42 C.F.R. 457.805." Arnold Decl., Ex. 8. Following the issuance of the August 17 Letter, Defendant disapproved New York's requested expansion based upon the requirements imposed in the letter, namely New York's failure to provide assurances that it met the 95% coverage requirement "outlined in an August 17, 2007, letter to State Health Officials . . . [as] are necessary" and its failure to demonstrate the cost-sharing requirements imposed in the August 17, 2007 Letter. Arnold Decl., Ex. 10 (emphasis added). Defendant never offered New York any opportunity to provide assurances that it has expanded the provision of health assistance to uninsured children effectively and efficiently in some manner other than guaranteeing 95% enrollment of the children below 200% FPL, nor did Defendant ever offer New York the opportunity to demonstrate that it utilized different reasonable procedures from those upon which Defendant insisted to prevent substitution.

Defendant's internal documents show that it disapproved New York's SPA #10 based precisely on the criteria of the August 17 Letter, namely because "the state did not demonstrate compliance with the 95 percent threshold for coverage below 200% of the federal poverty level," "the state indicated that it would not meet the 12 month uninsurance requirement to prevent

substitution" and the state's failure to demonstrate that its cost-sharing requirements would meet those in the August 17 Letter" Arnold Decl., Ex. 13. Defendant subsequently reiterated to New York that its disapproval was "consistent with the August 17, 2007, letter to State Health Officials." Arnold Decl., Ex. 12.

3. The Requirements of the August 17 Letter Have Immediate Binding Effects on the States.

Courts also consider whether "in the absence of the rule there would not be an adequate legislative basis for enforcement action [to] ensure the performance of duties." Sweet, 235 F.3d at 91. As noted above, state plans need only follow those requirements that are in statutes or codified regulations. 45 C.F.R. § 92.11(b). As Defendant concedes, none of the requirements in the August 17 Letter can be found in any statutes or codified regulations. Def. Mem., at 33.

Defendant has previously admitted that the existing statutes and regulations do not authorize it to effectively limit SCHIP expansions. HHS Secretary Michael O. Leavitt stated on July 31, 2007, "[u]nder current regulations [HHS has]... no authority to disapprove amendments solely based on income disregards." Gantz Decl., Ex. C. Additionally, in comments to the existing SCHIP regulation, Defendant acknowledged that states have flexibility to design their own substitutionprevention strategies:

[W]e note that the proposed regulatory text at § 457.805 [requiring the state to adopt "reasonable procedures" to address crowd-out] requires only that the State plan include reasonable procedures to prevent substitution. This approach permits State flexibility and implementation of policies based on the emerging research regarding substitution and on State experiences with substitution. . . . Although a period of uninsurance is one possible substitution prevention procedure, we invite States to propose other effective strategies to limit substitution. . . . State's substitution prevention efforts should be considered in the context of the entire State plan with consideration given to a State's particular needs and goals . . . States that choose to retain or impose periods of uninsurance are encouraged to include exceptions that help prevent the imposition of undue hardship under a range of circumstances, including loss of insurance through no fault of the family, extreme economic hardship, death of a parent, etc.

66 Fed. Reg. 2602-04 (Jan. 11, 2001).

As Defendant noted, it deliberately drafted existing regulations to afford flexibility to allow states to design substitution-prevention policies which best met their particular needs and goals. Because existing statutes and regulations do not provide Defendant the authority to impose one-sizefits-all substitution-prevention procedures upon all statutes uniformly, Defendant's attempt to modify existing statutes and regulations is invalid.

The August 17 Letter Is a New Position Inconsistent With Existing 4. Regulations.

When an agency adopts a new position inconsistent with its existing regulations, the agency must follow APA rulemaking requirements. Shalala v. Guernsey Memorial Hospital, 514 U.S. 87, 100 (1995). Courts routinely invalidate binding norms that agencies impose without following these requirements. See, e.g., CropLife America v. E.P.A., 329 F.3d 876, 881 (D.C. Cir. 2003) (EPA press release announcing a change in the use of data in determining the safety of pesticides constituted rule requiring notice and comment because the directive established an "obvious change in established agency practice," creating a new, "binding norm" that was "directly aimed at and enforceable against" the regulated community); U.S. Gypsum Co. v. Muszynski, 209 F. Supp. 2d 308, 310 (S.D.N.Y. 2002) (joint memorandum between two agencies establishing standards for pending and future applications constituted binding rules and required adoption through notice and comment requirements); Davidson v. Glickman, 169 F.3d 996, 999 (5th Cir. 1999) (Farm Services Agency Handbook that agency contended was an interpretive rule was invalidated because it imposed conditions beyond those that existed in current regulation, thereby affecting individual rights and requiring substantive rule-making); *U.S. Telephone Ass'n v. F.C.C.*, 28 F.3d 1232, 1234-35 (D.C. Cir. 1994) (Federal Communications Commission's schedule of fines for violations of the Communications Act issued without notice was invalid rule-making because the court found it difficult to believe the agency had any intention other than to "cabin its discretion" through the binding schedule, regardless of the "policy statement' clothing it wore"). In such cases, the court invalidates these norms because the new mandate "effectively amends a prior legislative rule." *Sweet*, 235 F.3d at 91. Particularly notable is *Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1028 (D.C. Cir. 2000), in which the court set aside the EPA's 19-page "Guidance" specifying how a State could conduct "periodic monitoring" for certain operating permits because the Guidance imposed standards beyond those contained in existing rule. *Id.*

Existing SCHIP statutes and regulations vest a great degree of discretion in the States to design their own program: "[w]ithin broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures." 42 C.F.R. § 457.1. While states should coordinate with private health plans and implement "reasonable procedures" to ensure SCHIP coverage does not substitute for private insurance, the regulations require only that states report what procedures they have determined, in their own discretion, to be reasonable. 42 C.F.R. § 457.805. This flexibility gives *states* the discretion to determine what procedures are reasonable, not Defendant. Mann Decl. ¶¶ 12-13. Defendant intentionally chose to leave the choice of procedures to the states. 66 Fed. Reg. 2602 (Jan. 11, 2001).

By the same token, the regulations authorize but do not require cost sharing. 42 C.F.R. §§ 457.505(a), 457.510–.560. They impose no pre-conditions for covering children above 250% FPL, other than the requirement that states also extend coverage to children from families with lower incomes as well. 42 C.F.R. § 457.320(b)(1). They do not require the state to regulate the behavior of the private-health-insurance sector. They do not require the state to ensure that private insurance coverage for children in the target population has decreased by no more than two percentage points over the preceding five-year period. They impose no waiting period, except in the case of premium assistance programs (requiring a six-month waiting period, with exceptions). 42 C.F.R. § 457.810.

Consistent with this flexibility, Defendant has previously and consistently approved SCHIP expansions above 250% FPL without imposing the August 17 Letter requirements. States have adopted various substitution-prevention methods, including waiting periods of different lengths and a variety of cost-sharing approaches. Mann Decl. ¶¶ 19-21. When states adopted waiting periods, Defendant encouraged them to include exceptions to prevent undue hardship. 66 Fed. Reg. 2604 (Jan. 11, 2001). Before the August 17 Letter, Defendant had never disapproved a state plan because of insufficient substitution-prevention strategies. Mann Decl. ¶ 22.

Now, by contrast, Defendant requires specific substitution-prevention strategies and will allow no exceptions for undue hardship. Arnold Decl. ¶¶ 19, 26; Ex. 9. Defendant will not approve SCHIP expansions that do not guarantee 95% enrollment of children below 200% of FPL or do not guarantee that the number of such children insured through private employers has not decreased by more than 2%. Arnold Decl., Ex. 9.

As with the requirements imposed by the EPA in a press release in *CropLife America*, Defendant's new requirements constitute an "obvious change in established agency practices,"

creating a new "binding norm" which is "directly aimed at and enforceable against" the States. *See CropLife*, 329 F.3d at 881. As with the standards imposed by memorandum in *U.S. Gypsum Co.*, the August 17 Letter requirements — 95% enrollment of children below 200% of FPL, and no decrease by more than 2% in the number of children in the target population insured by private employers — are "outcome determinative," resulting in disapproval of State Plan expansions similar to those which previously had been approved. *See U.S. Gypsum Co.*, 209 F. Supp. 2d at 309-10. As with the fine schedule imposed by the FCC in *U.S. Telephone Ass'n*, through the August 17 Letter, Defendant "cabin[ed] its discretion" regardless of the "policy statement' clothing it wore." *U.S. Telephone Ass'n*, 28 F.3d at 1235. Just as the courts invalidated the agencies' attempt to impose new requirements through fiat in those cases, the Court here should declare invalid Defendant's attempt to impose new, binding and enforceable standards by mere letter.

5. The August 17 Letter Is Not a Mere General Policy Statement or Interpretive Rule.

Defendant admits that the August 17 Letter requirements are a change in policy⁷ but argues that it may impose the new requirements upon states without following rule-making requirements because the requirements in the August 17 Letter are a mere "general statement of policy" or, alternatively, an "interpretive rule" which is exempt from rule-making. Def. Mem., at 37. As discussed above, Defendant's current characterization of the August 17 Letter is not entitled to deference, when the plain language of the letter and Defendant's application thereof demonstrate the letter imposes new, legally binding norms.

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⁷ Defendant also acknowledges that "an agency may not announce a change in position in a general statement of policy or interpretative rule that is contrary to existing regulations." Def. Mem., at 37. Defendant does not explain how its imposition of new requirements that states must meet but which are not included in statute or codified regulations is not contrary to 45 C.F.R. § 92.11(b). See Section A, supra.

a. General statements of policy may not impose a new binding norm.

When an agency issues a general statement of policy, that policy "does not establish a binding norm," and thus, "[t]he agency cannot apply or rely upon [that] policy as law because a general statement of policy only announces what the agency seeks to establish as policy." *Chamber of Commerce of U.S. v. Dept. of Labor*, 174 F.3d 206, 212 (D.C. Cir. 1999) (quoting *Pacific Gas & Elec. Co. v. F.P.C.*, 506 F.2d. 33, 38 (D.C. Cir. 1974)). The agency's treatment of its pronouncement illustrates whether it is a general statement of policy or a legislative rule in disguise:

The agency's express purpose may be to establish a binding rule of law not subject to challenge in particular cases. On the other hand the agency may intend merely to publish a policy guideline that is subject to complete attack before it is finally applied in future cases. When the agency states that in subsequent proceedings it will thoroughly consider not only the policy's applicability to the facts of a given case but also the underlying validity of the policy itself, then the agency intends to treat the order as a general statement of policy.

Pacific Gas & Elec., 506 F.2d at 39. The Pacific Gas court distinguished the order before it from the FCC statement in Columbia Broadcasting System, Inc. v. United States, 316 U.S. 407 (1942), which, unlike the order before it, was "couched in terms of command." Pacific Gas & Elec., 506 F.2d at 42. The Pacific Gas court also noted that in Columbia Broadcasting the issue in proceedings following its issuance was not the validity of the rule itself, but whether those regulated had complied with its terms. As such, the FCC was giving its pronouncement the "force of law" requiring rule-making, in contrast to the guidance offered by the order at issue in Pacific Gas. Id. at 43.

Defendant argues that the August 17 Letter "has no binding force" and that Defendant does not "rely upon [the August 17 letter] as law." Def. Mem., at 34-35. But like the FCC in *Columbia*

Broadcasting, Defendant has consistently relied on its August 17 Letter requirements as law. The August 17 Letter is expressed in mandatory language reflecting what states "must" include in SCHIP State Plan extensions. Arnold Decl., Ex. 9. It directs states to amend their previously approved state plans to be consistent with the new requirements in order to avoid "corrective action." Id. Defendant's follow-up communications with states instruct them to come into "compliance" with the "required crowd-out strategies and assurances." Gantz Decl., Ex. B; Tucker Decl., Ex. 3. Further, Defendant based its disapproval of New York's proposed SCHIP expansion plan entirely upon New York's failure to meet the August 17 Letter requirements, thereby framing the issue for any administrative challenge to the disapproval as whether or not New York's proposed SCHIP expansion meets the letter requirements, not on the validity of Defendant's policy choices imposed by such requirements. Indeed, Defendant's letter of November 30, 2007, to New York frames as an issue for New York's administrative challenge whether New York's plan amendment met Defendant's "August 17, 2007, State Health Officials' Letter [which] further articulated the procedures that Defendant would consider reasonable . . . including a period of uninsurance of at least one year, and cost sharing comparable to competing private plans subject to the overall 5percent family cap." Arnold Decl., Ex. 12. When an agency consistently treats its pronouncement as a binding limitation, the pronouncement equates to a legislative rule. Community Nutrition, 818 F.2d at 948.

Thus, *Pacific Gas & Elec.*, the sole case cited by Defendant to support its assertion that the August 17 Letter is merely a general statement of policy, does not support Defendant's position. Defendant cannot impose requirements which are binding on their face, command compliance with such requirements under threat of sanctions, apply the requirements in disapproving SCHIP State

Plan expansions, and thereafter claim the letter constitutes mere non-binding "guidance." As the court noted in *CropLife*, "the agency's characterization of its own action is not controlling if it self-servingly disclaims any intention to create a rule with the 'force of law,' but the record indicates otherwise." 329 F.3d at 883. *See also McLouth*, 838 F.2d at 1320-21 (holding that the "current claim" that model for predicting whether or not wastes included sufficient quantities of hazardous materials as to fall under regulatory requirements was non-binding statement of policy carried "little weight" and that agency's past characterizations, past applications, mandatory language, and unwillingness to re-examine model rendered model a legislative rule).

The first indication that Defendant has ever given that the August 17 Letter is not binding came in the instant litigation. Statements in litigation cannot have any weight when contrary to previous agency statements. *See Hoctor v. Dep't of Agriculture*, 82 F.3d 165, 171 (7th Cir. 1996) (holding that where agency had treated requirements as mandatory, agency's lawyer could not "amend its rules in order to make them more palatable to the reviewing court").

b. Interpretive statements may not impose new requirements.

Defendant alternatively argues that its August 17 Letter is an interpretative statement and thus exempt from notice-and-comment rule-making. Def. Mem., at 37-39. "An interpretive rule expresses the agency's view of what another rule, regulation or statute means." *Pacific Gas & Elec.*, 506 F.2d at 37 n.14. In other words, an interpretive rule must explain an existing requirement rather than imposing additional ones. The interpretation must logically come within the ambit of the statute or regulation which it purports to interpret. Defendant has not reinterpreted any existing statute or regulation, but rather has imposed entirely new requirements.

Defendant argues that the August 17 Letter merely interprets the regulation at 42 C.F.R. § 457.805, which requires states to "include a description of reasonable procedures" to prevent substitution of public coverage for private coverage. Def. Mem., at 37 (emphasis added). Even if this reporting requirement afforded Defendant any authority to determine what substitutionprevention procedures were reasonable, this would have no application to the other requirements of the August 17 Letter, such as the 95%-enrollment assurance and 2%-maximum-decrease-inenrollment assurance. In any event, Hoctor v. Dept. of Agriculture, 82 F.3d 165 (7th Cir. 1996), demonstrates that Defendant's position is untenable. In *Hoctor*, a codified regulation required secure containment for dangerous animals, but the Department memorandum specifically required eightfoot perimeter fences for wild cats, such as lions, tigers, and cougars. *Id.* at 168. The court rejected the Department's argument that its memorandum was merely its interpretation of the codified containment rule: "Eight feet is not part of the meaning of secure containment." Id. at 170. A policy to choose one method among many available is a legislative function requiring notice and comment so that persons affected can "communicate their concerns in a comprehensive and systematic fashion to the legislating agency." *Id.* at 171. Similarly, through its August 17 Letter, Defendant has settled upon a combination of very specific and detailed requirements without giving any opportunity to the States to inform Defendant of the likely consequences of such choices. See also United States v. Picciotto, 875 F.2d 345, 349 (D.C. Cir. 1989) (holding that Park service could not impose conditions on permits for demonstrations without notice and comment).

Finally, Defendant's argument ignores the principle that prevents an agency from effectively amending a prior legislative rule under the guise of an "interpretive rule" and thereby bypassing APA requirements. *See Sweet*, 235 F.3d at 91. Defendant is attempting to do just that through the August

17 Letter. The language of existing statutes and regulations in Defendant's own words allows states—as opposed to Defendant—to tailor their own substitution-prevention procedures, based upon their experience with substitution in their state: "We agree that State's [sic] substitution prevention efforts should be considered in the context of the entire State plan with consideration given to a State's particular needs and goals. To this end, we have retained a flexible regulatory requirement regarding substitution and indicated that [Defendant] will incorporate additional flexibility in its plan review process." 66 Fed. Reg. 2604 (Jan. 11, 2001).

CONCLUSION

Under 28 U.S.C. § 1331, this Court has jurisdiction to hear Plaintiffs' challenge to the

regulations of the August 17 Letter. Under 5 U.S.C. 701, et seq., Defendant has waived sovereign

immunity. Because the SCHIP statute does not provide any other forum for review of the regulations

of the August 17 Letter, this Court provides the sole forum, and this Court should deny Defendant's

motion to dismiss. By the same token, because Defendant promulgated these rules by letter rather

than the notice-and-comment process, Plaintiffs are entitled to partial summary judgment on their

claim that the rules are invalid for improper process and their claim that they are not required to

comply with them.

Dated: New York, New York

April 16, 2008

Respectfully submitted,

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49

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